SECTION 4.

DECISION-MAKING REGARDING FISH ADVISORY OPTIONS

4.1. Overview

This section contains a discussion of methods for comparing the characteristics of various management options to select the most appropriate options and levels of protection based on program goals, available resources, and local conditions. A discussion of both data organization and decision-making, as well as one of qualitative comparisons of risk, organizational features, and impacts are presented. Also addressed are decisions required for program design. The focus of this section is on qualitative comparisons among options, although the use of quantitative information is encouraged. Many factors, such as cultural and other social impacts, cannot be quantified, or easily compared to quantitative risk or economic data.

Templates are provided that can be used by risk managers to organize information on option characteristics. These templates utilize information discussed in other sections of this volume (e.g., risk levels, options). Issues related to prioritizing impacts are discussed along with methods for program evaluation and modification.

4.2. Qualitative Comparisons of Health Risks and Options Impacts

The information discussed in other sections and volumes should be used to evaluate overall advantages and disadvantages of various program options. The information includes:

- organizational impacts including feasibility and efficacy (Section 2),
- societal impacts including nutritional, cultural, and economic impacts (Section 3), and
- population risk characterization (Supplement B in Volume II).

The information can also be used to prioritize activities. It is suggested that the planning and evaluations for fish advisories be carried out on a site-specific basis whenever feasible. As discussed previously, local population characteristics and impacts on local traditions and economies may vary considerably from one area to another.

Various types of information are required for decision-making. Some may be of a quantitative nature (e.g., risks associated with current consumption patterns, the estimated costs of various program activities, staffing requirements, impacts on property values). The quantitative values may be best estimates; however, this type of predictive information often contains significant uncertainty and should be considered accordingly. Most information collected for a fish advisory program will likely be of a qualitative nature (e.g., potential cultural impacts on targeted populations, nutritional impacts).

Some form of risk characterization is also assumed to have been generated, although it may not be precise and should be considered a rough estimate even when detailed analyses have been carried out. (Risk characterization is discussed in Supplement B.) Federal risk assessment methods were designed primarily to provide a means to establish exposure limits (e.g., for drinking water standards) and generate protective rather than predictive estimates. Consequently, the risk estimates should be considered an indication of maximum risk rather than a precise predictor of actual risk. As discussed previously, risk reduction through implementation of fish advisory programs are characterized as "benefits" for purposes of discussing advantages and disadvantages of various options. Benefits are those cases or people who would have been affected that were not affected as a result of reductions in their consumption of contaminated fish.

A wide variety of risk management options have been considered in this document. The selection of which options to consider for inclusion in a fish advisory program is a critical decision. Risk managers may have wide latitude in establishing fish advisory programs or they may be operating under a specific set of constraints regarding their options for reducing fish-related risks. Restricting access to waterbodies or banning fishing may not be an option in areas where no regulatory authority is held by the overseeing fish contamination problems. (In most areas, however, the health department will have authority to restrict access in cases where a clear and present danger to the public exists.)

Significant constraints on program options may also be imposed by budgetary or other conditions. Because the options have differing potentials for reducing risk, restricting options may affect a program's risk reduction potential significantly. The full spectrum of risk management options should be considered prior to selecting

a particular subset of activities. This approach enables risk managers to review the advantages and disadvantages of all possibilities with other interested parties, so that the final decisions may be considered objective and fully thought through.

Table 4-1 provides a template for organizing information on the various impacts, resource needs, and benefits of program options. This template provides only a small amount of space for information entry in any category. Indicators of effect may be used instead of long narrative descriptions; alternatively, risk managers may use this template as a model to modify according to their needs. Information should be organized by water body and/or targeted population. One set of data could be generated for each subpopulation, allowing decisions to be made more easily on a site-specific basis. This method is recommended because the characteristics of each group may differ.

Restriction of fish consumption involves tradeoffs with respect to health, recreation, economics, community and traditional activities, and personal interests and other perceived benefits of fish consumption. Risk managers are encouraged to consider all risks and impacts in some way; however, managers may elect to focus on one or a few of the potential risks or impacts. The types of options and the degree of restrictiveness than a fish advisory program recommends will depend, in part, on the way in which various population groups and their risks are evaluated and upon the impacts considered most important. Decisions regarding how risks and impacts are prioritized and balanced will have a pronounced effect on fish advisory programs. Involvement of all affected parties in the evaluation and decision-making process is highly recommended.

4.3. Selection of Options

Risk managers, in concert with other policy makers, scientific and health advisors, and community members, will recommend the most appropriate options for dealing with fish contamination. In large programs, such as state programs, an array of options may be chosen corresponding to specific

Table 4-1. Information Summary on Organizational Factors, Impacts and Benefits: Template[1]

Risk Management Options	Feasibility			Efficacy		Nutrition	Cultural Impacts		Economic Impacts	Health Benefits	
	Staff	Funds	Reg. Auth.	Education	Risk Reduction		Traditional Activities	Diet		Non-Cancer	Cancer
No action											
Fish advisories											
General											
Quantitative											
Catch and release											
Voluntary											
Mandatory											
Fish ban											
Voluntary											
Mandatory											

[1] This template is for entry of information in any form which is useful to risk managers. This may be descriptive or quantal information, such as high, medium and low, or quantitative information such as number of staff required, costs of programs, etc. It is not anticipated that governing bodies will have detailed information on all categories included; however, this template may be used to organize the inforamtion which has been collected.

contamination characteristics, risk, targeted populations, and resources. It is assumed in this document that most decisions will involve the use of general or quantitative fish advisories in areas where contamination is known to exist at levels posing significant population risks. As discussed in Section 2, however, determining what level of risk is significant is an agency decision, and will affect the scope and nature of fish advisory programs.

The selection of appropriate fish advisory options is obviously a critical decision (as defined in Section 1) in program development. While this appears to be the most important decision, it usually will be based upon information gathered regarding individual or community risk levels and characteristics. This information, in turn is dependent on previous decisions regarding consumption rates, sampling and analysis, risk value selection, target population identification, evaluation of non-fish exposures, and consideration of impacts. These factors have been discussed in previous sections of this document and are summarized in Table 1-1. Because all previous decisions contribute to the basis for option selection and determination of protection levels, it is suggested that risk managers review these initial decisions prior to making the final decisions discussed in this chapter.

It is useful to evaluate whether previous decisions were health conservative or not; whether they took into account all or some of the population; whether they focused on average, high end, or bounding exposure and risk values; and other factors. Such information can be used when evaluating options and advisory levels to arrive at appropriate choices. If conservative assumptions were used in previous decisions, there may be less concern that compliance with advisories be strictly adhered to. Alternatively, if average values were used and sensitive populations were not targeted, non-compliance with advisories could have significantly greater adverse effects.

In selecting specific fish advisory options, risk managers may want to consider carefully which strategies are likely to be most effective for the populations which are to be served. This group is typically made up of several populations near various waterbodies and may require separate evaluation of each case. Information on the likelihood that a group will benefit from a particular approach can be inferred from the data collected on cultural, economic, and nutritional impacts. In addition, any other anecdotal or local information with a bearing on this type of decision should be considered. Such decisions are not necessarily based solely on objective data, and may require a familiarity with and sensitivity to the targeted population.

Practical considerations regarding sample quantitation limits are also relevant. Some contaminants may not be quantifiable at levels which are as low as those

indicated as optimal by health risk data. For example, quantifying the concentrations may not be possible at levels yielding a cancer risk of one in one million. This practical constraint may be important in establishing a realistic advisory. In some cases it may necessitate the acceptance of a higher level of risk than would be chosen based solely on health considerations. Flexibility in the program design will allow for modifications in advisories over time in keeping with more sensitive assays likely to be developed in the future.

Risk managers may elect to base option selection largely on risk. An example of this type of approach follows:

- A governing body could elect to take no action when cancer risks were less than one in one million and the concentrations were significantly less than the RfDs for non-carcinogens.

- General advisories could be developed when cancer risk levels were in the range of one in one hundred thousand to one in one million and the RfDs were not exceeded but were approached.

- Quantitative advisories could be developed for carcinogens with risk levels greater than one in ten thousand but less than one in one thousand and when the RfDs were exceeded by a factor of up to ten.

- Fishing bans and/or catch and release programs (either voluntary or involuntary) could be used when cancer risks exceeded on in one thousand and RfDs were exceeded by a factor greater than 10.

This tiered approach provides a spectrum of activities to deal with negligible to serious risks. This is only an example; risk managers may decide to structure their programs quite differently. Decisions should be made in the context of previous decisions and include considerations of whether previous decisions were sufficiently health conservative. As discussed throughout this document, decisions should also take into consideration the characteristics and needs of local affected communities.

The tiered approach is an overall strategy that may be applicable to all areas within a governing body's jurisdiction. It is risk-based and its application to specific waterbodies and populations requires risk information. Consequently, risk calculations may be carried out (see Supplement B in Volume II) requiring contamination data, consumption patterns, risk values, and body weight data. Table 4-2 provides a template that risk managers may use to organize

Table 4-2. Tiered Approach to Fish Advisories	
Risk Level	Option
Cancer	
Non-Cancer	
Other Considerations	

information for a tiered approach to risk reduction. Note that both cancer risk and non-cancer risk entry cells are provided. The advantages and disadvantages of selecting various values for the parameters used in this table are discussed throughout this text.

This approach is especially sensitive to decisions regarding consumption patterns and risk values. Contamination data are obtained through sampling and so not subject to alterations. Body weight data, while important, will usually not alter final results significantly. For example, the use of a 60 kg body weight for women will result in an "allowable" level of contamination which is only 15 percent lower than that for a 70 kg man. Approaches based on children's body weights may have a more substantial impact. Consumption patterns may vary widely within and among populations. The rate of 6.5 g per day is less than one tenth that observed in many studies of subsistence fishers, some of whom consume considerably more than 100 grams per day. For example, a recently completed study in the Great Lakes found that the average fisher consumed 360 grams per day (GLIFWC, 1994). Selecting a consumption rate is therefore a critical factor in establishing where fish advisories are needed and the nature of the advisory programs. It may be advisable to develop criteria based on different consumption rates for populations with widely varying consumption patterns.

Risk values are also a critical parameter in making decisions regarding advisory programs. Supplement B discusses the importance of selecting an appropriate health endpoint (e.g., developmental, systemic, non-carcinogenic) and its potentially significant impact on the level of contamination considered to pose unacceptable risks. As the discussions of individual chemical contaminants in Volume II demonstrate, many contaminants are associated with numerous different types of toxicity that may be exhibited at different levels of exposure. Recent developmental toxicity, neurotoxicity, or immunotoxicity data may indicate that risk occurs at lower levels of exposure than those indicated by previous liver and kidney toxicity studies. (The organ that is most sensitive will vary by chemical.) The use of the most sensitive endpoint will result in a more conservative approach to health protection.

Carcinogenic toxicity has in the past often yielded the most health-conservative exposure limits, especially when coupled with a low level of "acceptable" risk such as one in one million. Decision-makers may elect to choose a non-cancer health endpoint or a less stringent level of acceptable risk. For some chemicals there may be alternatives to choose from regarding risk endpoints and values varying by

orders of magnitude. The decisions will affect the scope and nature of a fish advisory program and the level of protection afforded the public substantially. Careful consideration of the advantages and disadvantages of the decisions regarding risk parameters is strongly encouraged.

Table 4-2 contains separate entry areas for other considerations that decision-makers may feel are important. These may include specific concerns regarding special sensitivities or types of effects that risk managers may feel justify an alternative approach. An example of this might be when new toxicity data become available. Under these circumstances, risk assessors may provide a new analysis that is used in developing fish advisories. An example is provided by mercury, which has been carefully evaluated by some states and subsequently stringent guidance was developed. Evidence of mercury toxicity is provided in human studies and causes serious effects in offspring of exposed women and exposed infants, as discussed in Volume II. These factors have led some risk managers to approach this chemical more aggressively than other contaminants. Risk managers may also elect to address other developmental toxins with greater conservatism due to concerns regarding exposures of pregnant women. Significant toxicity data gaps, the existence of known highly sensitive individuals in a population, or other predisposing factors such as poor nutritional status may lead risk managers to vary their options selections.

4.4. Levels of Protection

When fish advisories are considered necessary, risk managers will determine the level of protection in a fish advisory to be afforded targeted populations. Risk managers may choose from various risk values (e.g., RfDs and cancer potencies, locally generated values) to establish consumption limits. These values will result in consumption limits varying by orders of magnitude, especially when cancer-based and non-cancer-based values are compared. In addition, targeted "acceptable" risk levels are used in setting limits for carcinogens. Decisions regarding risk values can have a substantial impact on consumption limitation policies and on potential risks to the population.
This is discussed in some detail in Supplement B of Volume II.

The consumption limits, listed in Volume II, provide different levels of protection from carcinogenic risk, ranging from one in ten thousand to one in one million upper bound lifetime likelihood of cancer. Consumption limits corresponding to these different risk levels in risk multiples of 10 are provided; however, the methodology to calculate consumption limits for other risk levels is also described, and can be used when appropriate. Cancer risks are evaluated based upon an assumed

relationship between exposure and lifetime risk as defined in the cancer potency values for each target analyte. Risk managers determine what level of risk is acceptable (e.g., one in ten thousand, one in one million), which enables them to identify a particular exposure level as acceptable. The acceptable level of risk can be determined by the needs and goals of the target population, the decision-makers, other affected parties, or, under ideal circumstances, by joint discussions between the various impacted groups and agency staff.

Consumption limits based on non-carcinogenic effects typically use an RfD or other benchmark approach to determine a "safe" exposure level. The potential for non-carcinogenic effects can be evaluated by comparing exposures quantitatively to a Reference Dose (RfD) or some other benchmark of a "safe" exposure level (Supplement B in Volume II). Volume II provides the RfDs developed by EPA, along with a summary of toxicological information for the 23 target analytes. It also includes discussions of recent study results for most analytes regarding developmental, neurological and other types of toxicity. As discussed in Volume II, risk assessors may elect to use the EPA RfDs or review of the toxicological literature and develop their own exposure limits, based upon which values they consider most appropriate for their target populations. In some cases, more than one value may be selected for various subgroups of the population (e.g., children, women of reproductive age).

Table 4-3 provides a template to be used to list the selected values for contaminants in a particular waterbody, or which are of concern to a particular population. If a population fishes from more than one waterbody it may be advisable to include all chemical exposures in one evaluation so that similarly acting chemicals can be identified. The template includes entry areas for a variety of population subgroups and for various body weights of children. Risk managers may decide to refine their advisories to this level, or may determine that one general advisory is sufficient.

Consumption limits are provided in Volume II and offer various options from which to choose. Consumption limits for children are based on one body weight in Volume II; however, methods for calculating consumption limits for other body weights are also provided in that volume. Adult consumption limits are based on a 70 kilogram body weight for the general population and for women. Risk assessors and managers may determine that their female population of reproductive age has a different average body weight, or that a lower than average body weight should be used to provide a more health conservative values. Methods for calculating new consumption limits (or modifying the limits provided in the tables listed in Volume II) are also provided.

Table 4-3. Template for the Summary of Advisory Levels

Contaminant	General Advisory	Basis	Women's Advisory	Basis	Children's Advisory			Basis	Other	Basis
					Body Weight	Body Weight	Body Weight			

Decisions regarding the establishment of fish intake limit levels are at the discretion of the agency issuing fish advisories. The federal agencies, including EPA and FDA, who provide information and support in this area, do not have regulatory authority over non-commercial fish. Agencies are encouraged to establish limits which are most appropriate for their target populations in the context of local needs and characteristics.

4.5. Level of Program Effort and Funding

As discussed in Section 2, programs utilizing similar options (e.g. quantitative fish advisories) may differ substantially due to differing levels of effort and funding. Financial constraints may be moderate or severe, depending on the financial circumstances of the agency. These constraints affect the manner in which options can be implemented and may be a consideration in selection of an option as discussed in Section 2. The level of program effort and funding is a critical decision which is often beyond the scope of the risk manager. Risk managers may wish to maximize the available resources through cooperative activities with other agencies carrying out similar work, community groups with similar goals, or health or environmental organizations having similar interests (this is briefly discussed in Section 3).

Discussions of organizational structures and staffing for fish advisory programs are beyond the scope of this document. There are numerous public management guidebooks, however, providing information on effective and efficient management structures and program design that could maximize the effectiveness of a fish advisory program regardless of its size (Gawthrop,1984; Koteen, 1989; Bryson, 1988 and 1992; Frederickson, 1980; Vasu, 1990; Campbell, 1988; Gilbert, 1983; Association for Public Policy Analysis and Management, 1982; Carr, 1990). Readers are urged to consult these sources, as well as states and other groups that have set up fish advisory programs, to identify approaches that can be used to meet their goals using available resources.

A significant consideration in evaluating the type of fish advisory program that can be set up using a particular resource allocation is the overall population to be served. This population is typically made up of several sub-populations near various waterbodies, that may have different consumption patterns, risks, and likelihood of compliance with advisories. Within the constraints imposed by available resources, risk managers must determine which groups are in the greatest need of services and how those groups will best be served. Moderate services may be provided to a larger number of groups, or especially high-risk groups may be targeted for intensive efforts. The utilization of all types of information previously

discussed in this document may be helpful in determining the best approach to this type of resource allocation problem. Consultation with affected parties is also encouraged, because they may have strategies for accessing other resources to address program goals.

4.6. Program Evaluation and Modification

When a fish advisory program is being designed or modified, risk managers may want to consider inclusion of a component that involves program evaluation and modification. These activities are often not considered in the initial planning of a program, but an efficacy review in a program can help managers determine how effective it is (who it is reaching, whether their behavior has changed, whether the target population wants additional information, etc) and how the program might be altered to better address its goals. This type of activity can be carried out informally through contacting local participants and members of the targeted population routinely, or may be more formally designed to sample effectiveness randomly through surveys or some other means.

Incorporating flexibility into fish advisory programs is important so that necessary modifications can be made both in the initial design and over time as needs change. The decision to include these elements in a program design is one the risk managers should consider carefully to provide for the long-range success of a fish advisory program. The decision to include these components in a fish advisory program is considered critical because it may have a substantial impact on a program's long-term success.

4.7. Summary

This section has provided methods for organizing and considering information regarding risk, organizational issues, and impacts of fish advisory options. Risk managers and others involved in the decision-making process may need to utilize information from a variety of sources to gain an overall sense of who needs to be served by fish advisory programs and how to best design a program. As with any public undertaking, all problems and issues cannot be anticipated. Consequently, program flexibility is necessary to ensure long-term effectiveness. By broadly considering the characteristics of the target populations, however, risk managers will be better able to design programs appropriately (this is also addressed in

Volume IV: Risk Communication). When decisions are made and programs are designed with participation from representatives of targeted populations, valuable insights into the community are gained and the opportunities for a successful program are increased.

The Agency recognizes that there is much valuable information that can be obtained through the experiences of people in the field who are working on the development of fish advisory programs. EPA welcomes contributions from these people. Future versions of this document will benefit from information which readers submit.